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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,144

03/25/2004

Robert Costa

03-284-E

7397

20306

7590

12/27/2007

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EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

12/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/809,144

Applicant(s)

COSTA ET AL.

Examiner

Mark Halvorson

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/26/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3, and 8-10 are pending and are under examination.

35 USC § 112 1st paragraph rejection maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-3, and 8-10 for failing to comply with the enablement requirement is maintained.

Applicants argue that the claims are fully enabled by the specification because the specification teaches one of skill in the art how to make and use the claimed invention without undue experimentation, and that Applicants are not required to present *in vivo* testing data; and that the *in vitro* results reasonably correlate with the *in vivo* results. Applicants state that the court has held that with respect to the *in vitro/in vivo* correlation, a rigorous or an invariable exact correlation is not required, so long as there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity and cite *Cross v Iisuka*. Applicants argue that a method for inhibiting *in vivo* tumor proliferation using a biological compound, such as a peptide, by itself does not suggest any inherently unbelievable undertaking or involve implausible scientific principles.

Applicants' arguments have been fully considered but are not found persuasive. First, in *Cross v Iisuka* the court stated that the *in vitro* pharmacological activity of the compound at issue was generally predictive of *in vivo* test results. Furthermore, the compound at issue was structurally related to another compound well known in the art with a similar function. The court in *In re Brana* based their finding on a comparison

between related compounds. Here, Applicants have not provided any evidence that a related compound functions similarly to their compound either *in vitro* or *in vivo*. Furthermore, the present claims are drawn to a method of inhibiting proliferation of a tumor cell *in vivo*. As stated in the June 27, 2007 Office Action the art of treating cancer is a highly unpredictable area, As such more guidance is required than other areas. Although *in vivo* data is not required it is one factor to consider and is especially relevant in highly unpredictable areas. Furthermore, the guidance in the specification and the *in vitro* working examples in the specification are not commensurate in scope with the present claims. The claims are drawn to a method of inhibiting proliferation of a tumor cell whereas the working examples in the specification demonstrate that the protein fragment of SEQ ID NO:10 inhibited the colony formation of a human osteoblastoma cell. Given the significant differences between the various types cancer and the unpredictability of treating cancer one of skill in the art could not predictably treat any type of cancer with the protein fragment of SEQ ID NO:10.

Applicants also submit a Declaration by Dr Wang and state that the post-filing date *in vivo* data supports enablement of the specification. The Declaration shows that the protein fragment of SEQ ID NO:10 injected intraperitoneally into tumor-bearing mice, penetrated into liver cells *in vivo* and altered Foxm1 cellular localization *in vivo*. The Declaration also shows that the protein fragment of SEQ IDO:10 inhibited hepatocellular tumor proliferation *in vivo*.

The Declaration of Dr Wang and Applicants arguments have been fully considered but are not persuasive. The document must present a showing of enablement which is commensurate in scope with the claims or at least as much of the claims as have been objected to *In re Armbruster*, 158 USPQ 152. The examples present in the Declaration must be sufficient to show enablement for the entire scope of the claimed subject matter. The Declaration demonstrates that the protein fragment of SEQ ID:10 inhibited hepatocellular tumor proliferation *in vivo* but the claims are drawn to a method of inhibiting proliferation of any type of tumor. Thus, the showing of enablement of the Declaration is not commensurate in scope with the present claims.

Given the disclosure in the specification and the Declaration one of skill in the art could not predictably treat any type of cancer with the protein fragment of SEQ ID NO:10.

Therefore, in view of the breadth of the claims, lack of guidance in the specification, the narrow scope of the working examples in the specification and the Declaration and the state of the art it would require undue experimentation to practice the invention as broadly claimed.

Summary

Claims 1-3, and 8-10 stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the

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examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson
Patent Examiner
571-272-6539

/Misook Yu/
Primary Examiner, Art Unit 1642